Automated telephone communication systems for preventive healthcare and management of long-term conditions (Protocol)

Cash-Gibson L, Felix LM, Minorikawa N, Pappas Y, Gunn LH, Majeed A, Atun R, Car J

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[Intervention Protocol]

Automated telephone communication systems for preventive healthcare and management of long-term conditions

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

- To assess the effects of automated telephone communication systems (ATCS) compared with usual care, for improving primary preventive healthcare and management of long-term conditions in terms of: 1) behavioural change; 2) clinical outcomes; 3) process outcomes; 4) cognitive outcomes; and 5) adverse outcomes.
- To determine which type of ATCS is most effective for primary preventive healthcare and management of long-term conditions.
- To explore which interventional design components may contribute to positive consumer behavioural change.

BACKGROUND

Description of the condition

Primary preventive healthcare

Primary preventive healthcare focuses on keeping people well, protecting healthy people from developing a disease, preventing them from experiencing an injury, or educating them to adopt lifestyles that enable them to lead healthier lives (Family Health Teams 2006). Primary prevention strategies can be of two types: health promotion and disease prevention (Figure 1). There is evidence to suggest that disease prevention strategies can protect children from preventable infectious diseases (e.g. child immunisation against polio, diphtheria, and mumps) (Salisbury 2006). Similarly, evidence suggests that people engaging in health promotion strategies (e.g. education and counselling that promote smoking cessation) are less likely to develop long-term conditions (Pearson 2002).

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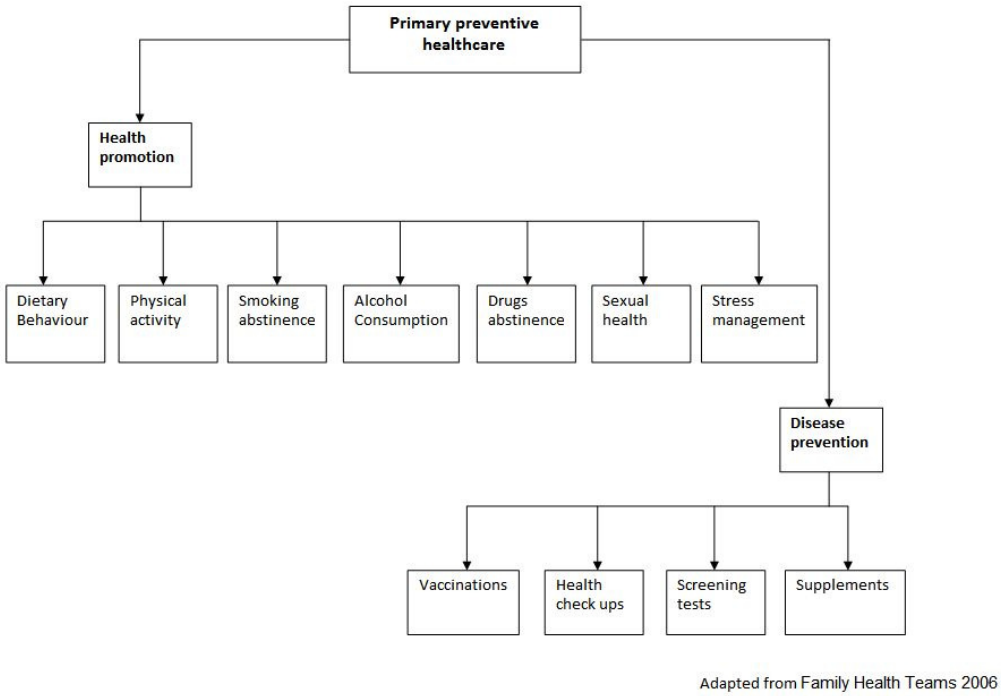
Figure 1. Primary preventive healthcare



Adapted from Family Health Teams 2006

A major challenge for healthcare systems is to deliver preventive activities that systematically target a number of cognitive, behavioural, physiological and affective factors that may be contributing to ill health (Gullotta 2003). In the prevention of type II diabetes, for example, a combination of cognitive, physiological and behavioural factors (such as lack of knowledge around risk factors, lack of physical activity, and unhealthy diet) may contribute to the development of the condition. An effective preventive strategy would therefore need to take a holistic approach and target each of the influencing factors (Figure 2).

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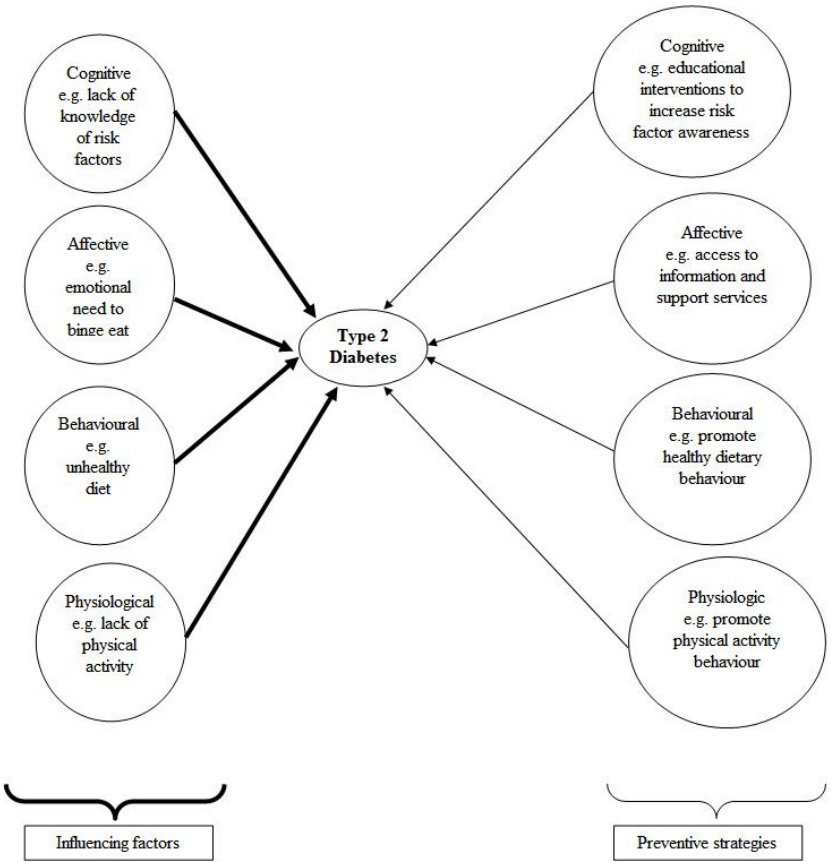
Figure 2. Influencing factors and preventive strategies in type 2 Diabetes



Central to devising an effective primary preventive strategy is to have a complete and accurate account of the influencing factors and their effects on individual and public health. Equally important is that preventive activities are optimally delivered by appropriate interventions to reach the greatest number of individuals. One possible method of communicating preventive activities to the population is via information communication technology.

Management of long-term conditions

Long-term conditions such as cardiovascular disease, cancer, diabetes, and chronic lung disease, are the leading causes of death globally (Alwan 2010). People with long-term conditions face challenges such as dealing with complex symptoms, medication regimens, disability, and lifestyle adjustments (Demiris 2004; Wagner 1998; Wagner 2001). Disease Management Programmes consist of a group of coherent interventions designed to manage one or more long-term conditions (and prevent a worsening state of condition) using a systematic, multidisciplinary approach employing multiple treatment modalities (Schrijvers 2009; Weingarten 2002). Disease Management Programmes may include self-monitoring and self-management interventions, patient and provider education, individualised care plans, and telemedicine (RAND 2010; Webb 2006). They can lead to:

- improved control of long-term conditions;
- improved clinical processes of care (e.g. adherence to evidence-based guidelines) (Weingarten 2002);
- improved quality of life;
- reduced hospital admission rates (Brandt 2010; Mattke 2007); and
- prevention of premature death (Alwan 2010).

Effective Disease Management Programmes can bring together relevant information systems with continuous follow-up and targeted management and can incorporate information communication technology to provide accessible and convenient educational

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information as well as self-management tools for people with long-term conditions.

Emerging uses of information communication technology in primary preventive healthcare and management of long-term conditions

Today consumers increasingly use information communication technology to:

1. access their own medical records through web portals;
2. communicate online with others, whether on a personal basis or in a virtual community;
3. surf the Internet to find information about health and health services; and
4. transmit health data or communicate messages using the web or the telephone (Pappas 2011).

The use of information communication technology applications to facilitate communication in health care has emerged through consumer demand and government initiative (Dansky 2006; Gupta 2008). This may facilitate active participation of consumers in managing their own health (Maheu 2001). There is some evidence that tools such as automated telephone communication systems (ATCS) can be successfully used to: deliver health information to consumers which facilitates health promotion (Estabrooks 2009; Oake 2009); enable the active participation of consumers in managing their own care; and facilitate epidemiological and public health research by utilising collected patient data (Maheu 2001).

Information communication technology can also lend itself to the delivery and administration of Disease Management Programmes. There is evidence that ATCS can be successfully used to deliver health information to patients which facilitates management of long-term conditions (Derose 2009; Oake 2009).

Description of the intervention

ATCS incorporate a specialised computer technology to deliver voice messages and collect information from consumers using either their telephone's touch-tone keypad or voice-recognition software (Piette 2001). ATCS can be of three types:

1. Uni-directional ATCS enable non-interactive voice communication and use one-way transmission of information or reminders (Parikh 2010).
2. Interactive ATCS (e.g. Interactive Voice Response Systems) enable real-time communication to provide feedback and individualised interventions (Lee 2003; Reidel 2008). In addition, they can be used as a data collection tool (Levin 2006). Interactive ATCS have been used for the management of diabetes (Graziano 2009; Piette 2000; Schillinger 2009), heart failure (Weintraub 2010), coronary heart disease (Reid 2007), and asthma (Bender 2010). They have also been used in health promotion initiatives, including dietary behaviour (Delichatsios 2001), physical activity (Pinto 2002), and substance use (Alemi 1996).
3. 'ATCS Plus' interventions include ATCS with additional functions, as described below (Webb 2010):
    - Advanced communicative functions include: access to an advisor to request advice (e.g. 'ask the expert' facility), scheduled contact with an advisor (e.g. telephone or face-to-face meetings), and peer-to-peer access (e.g. buddy systems).
    - Supplementary functions include: automated, non-voice communication e.g. email and short messaging service (SMS).

How the intervention might work

ATCS act as a mode of communication by which evidence-based decision support can be delivered to consumers to enhance their self-management skills, and thus empower them to effectively manage their conditions (Bodenheimer 2002; Corbin 1988; McCorkle 2011).

There is a growing recognition that ATCS interventions should be informed by theoretically-driven models (Krupinski 2006; Revere 2001), such as the social cognition models. These include the: 1) Trans-theoretical Model (Prochaska 1984); 2) Theory of Planned Behaviour (Ajzen 1985); 3) Health Belief Model (Rosenstock 1974); 4) Self-efficacy Theory (Bandura 2001); and 5) Self-regulation Theory (Leventhal 1984). Self-management skills can be developed using any of the social cognition models (Barlow 2002). There is evidence to suggest that behaviour change interventions underpinned by a theory can significantly enhance health behaviours (Fisher 2007; Michie 2009; Webb 2010). Figure 3 provides a conceptual framework on how theories can influence healthy behaviour.

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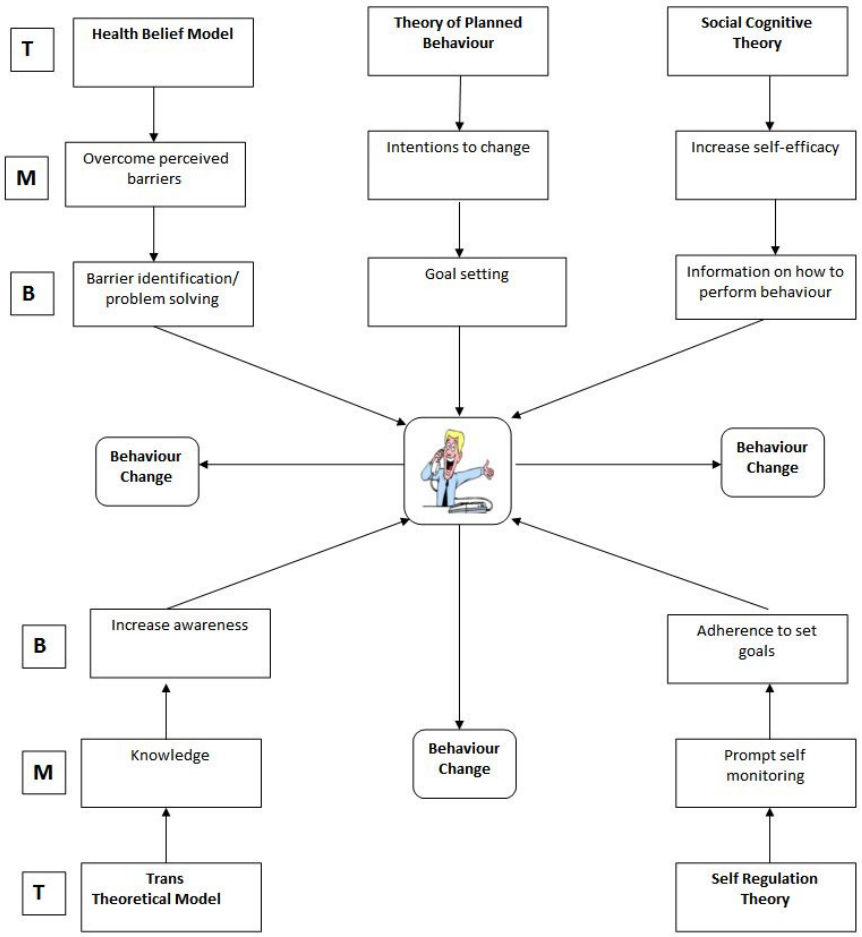
Figure 3. Conceptual framework of ATCS in preventive healthcare



T: Theory; M: Mediator; B: Behaviour change technique

Social cognition models assume that any health outcome is the consequence of the complex interaction between social, economic, psychological and biomedical factors (Edelman 2000; Kelly 2009). These models focus on key concepts, such as self-efficacy and attitudes to influence behaviour, which in turn can lead to behaviour change (Hardeman 2005; Michie 2010).

Healthcare interventions delivered using Disease Management Programmes, such as the Chronic Care Model, have produced improved consumer care and health outcomes (Lee 2011; Piatt 2006; Schillinger 2009). According to this model, management of long-term conditions requires an interaction between a prepared, proactive practice team and an informed, engaged consumer (Wagner 2002). This can be implemented through the interaction of elements such as self-management support, delivery system design, decision support, and clinical information systems for optimal delivery of healthcare (Wagner 1998; Webb 2006). Figure 4 describes a framework illustrating how ATCS in the management of long-term conditions, using the Chronic Care Model, might work.

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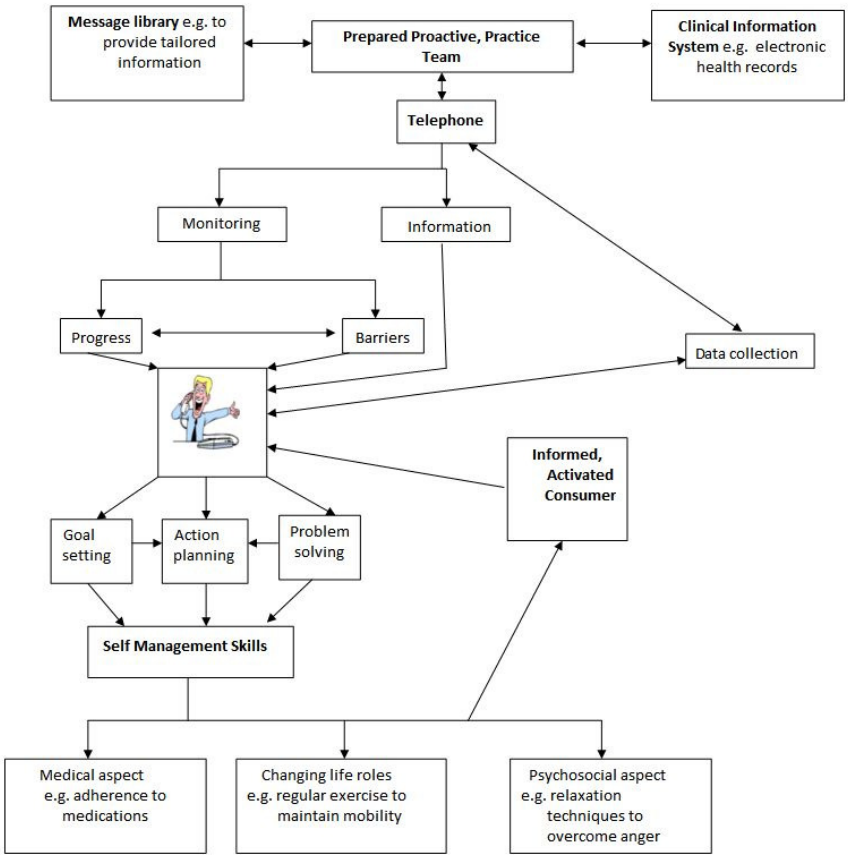
Figure 4. Conceptual framework of ATCS in the management of LTCs



Advantages of automated telephone communication systems

ATCS as a data collection tool have a number of advantages over traditional face-to-face consultation. These include convenience, simplicity, anonymity and low cost (Friedman 1998; Lee 2003). ATCS provide access to health care 24 hours a day, 7 days a week (Schroder 2009), and immediate feedback to the consumer (Hall 2000). Patients and healthcare professionals using ATCS have reported a high degree of user satisfaction, noting that it is both user-friendly and convenient (Abu-Hasaballah 2007; Hall 2000). ATCS technology has been shown to facilitate access to difficult-to-reach populations (i.e. people from a lower socioeconomic background) as ATCS require access only to a telephone (private or public) (Piette 1999; Schroder 2009). ATCS have also been shown to be acceptable to low-literacy populations (Glasgow 2004; Piette 2007) and frail elderly patients (Mundt 2001). Unlike face-to-face interaction which can elicit socially desirable responses leading to under-reporting of stigmatising behaviours and over-reporting of socially desirable behaviours, ATCS have been found to elicit greater self-reporting of sensitive issues (e.g. substance use, alcohol use and sexual history) by reducing self-reporting bias (Alemagno 1996; Perrine 1995; Schroder 2009). They also have the potential to reduce healthcare delivery costs (Friedman 1997; Friedman 1998; Piette 2001).

Disadvantages of automated telephone communication systems

Programming of ATCS involves investment in software and hardware, for example to enable multiple simultaneous call-ins and call-outs and the development of a script appropriate for the target population and the topic of investigation (Piette 2007; Schroder 2009). ATCS may also present difficulties with the provision of immediate participant support; should questions arise during the interview (Schroder 2009), ATCS cannot capture, interpret, and respond to the users' non-verbal responses (Williams 2001). Individuals with physical disabilities (e.g. severe loss of hearing or speech) may have difficulty accessing ATCS (Mundt 2001). Oth-

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ers may simply have a strong preference for interactions with humans rather than with ATCS (Mahoney 2003). In addition, for individuals targeted by several ATCS-based interventions, ATCS could lead to information overload and outright rejection of the interventions. Finally, protection of individually identifiable health information could be a challenge.

Why it is important to do this review

Existing reviews found evidence of effectiveness of ATCS in preventive healthcare or management of long-term conditions (Krishna 2002; Oake 2009). However, neither explored the theoretical basis nor the mechanism of action of the intervention. We will fill this gap by investigating the effects of interventions based on theoretical constructs, as well as explore the behaviour change techniques implemented in the intervention (Abraham 2008; Krupinski 2006; Michie 2005; Michie 2011). Where these have been used to inform intervention design in trials, we will seek to understand mechanisms of action by exploring potential mediators of behaviour such as knowledge, intention, self-efficacy, and emotions (Michie 2010).

In addition, it has not been identified which types of ATCS are most effective for primary preventive healthcare or management of long-term conditions in what setting, and for which condition. If the data permit, we will explore different interfaces of ATCS programme design and layout that may be used for diverse population groups (considering factors such as age, socioeconomic status, preferred language, and literacy) (Car 2004). Furthermore, healthcare providers such as 'Kaiser Permanente', and long-term conditions management companies such as 'Healthways' are contributing to the evidence base in the management of long-term conditions by evaluating ATCS' effectiveness in trials (Estabrooks 2009; Mosen 2010; Simon 2010; Hamar 2010; Rosenzweig 2010).

A new systematic review is thus needed to guide the implementation of ATCS in preventive healthcare and management of long-term conditions.

OBJECTIVES

- To assess the effects of automated telephone communication systems (ATCS) compared with usual care, for improving primary preventive healthcare and management of long-term conditions in terms of: 1) behavioural change; 2) clinical outcomes; 3) process outcomes; 4) cognitive outcomes; and 5) adverse outcomes.
- To determine which type of ATCS is most effective for primary preventive healthcare and management of long-term conditions.
- To explore which interventional design components may contribute to positive consumer behavioural change.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) and quasi-randomised trials (defined as: a trial where randomisation is attempted but subject to potential manipulation, for example using day of week, date of birth or sequence of entry into trial), interrupted time series (ITS) and controlled before and after (CBA) studies. We will include trials with individual and cluster randomisation.

We will include CBA and ITS studies as they are often used to draw conclusions about 'promising interventions' ready for trialling, when RCTs may be too expensive or simply impractical, or where there are insufficient RCTs on a particular type of preventive healthcare or long-term condition (Centre for Reviews and Dissemination 2008; Higgins 2011; Jackson 2005). ITS designs can address cyclical trends (i.e. the outcome may be increasing or decreasing over time such as seasonal or other cyclical observations). To be included, these studies must meet the criteria specified by the Cochrane Effective Practice and Organisation of Care Review Group (EPOC) (Ryan 2009). For CBA designs, the timing of data collection for the control and intervention groups should be the same, and there must be at least two intervention sites and two control sites and both groups should be comparable on key characteristics, i.e. with respect to demographics and intervention context. For ITS designs, the studies should have a clearly defined point in time when the intervention occurred and at least three data points before and three after the intervention.

Types of participants

- We will include consumers, including carers, who receive ATCS for primary preventive healthcare or management of long-term conditions, regardless of age, gender, education, marital status, employment status, or income.
- For management of long-term conditions, we will include consumers who have one or more long-term conditions concurrently (i.e. multi-morbidity).
- We will include consumers in all settings.

Types of interventions

We will include studies that evaluate either Uni-directional ATCS or Interactive ATCS. We will also include studies that compare different ATCS (e.g. Uni-directional ATCS versus Interactive ATCS and/or versus 'ATCS Plus') in order to compare the effects of different interventional designs on primary preventive healthcare or management of long-term conditions.

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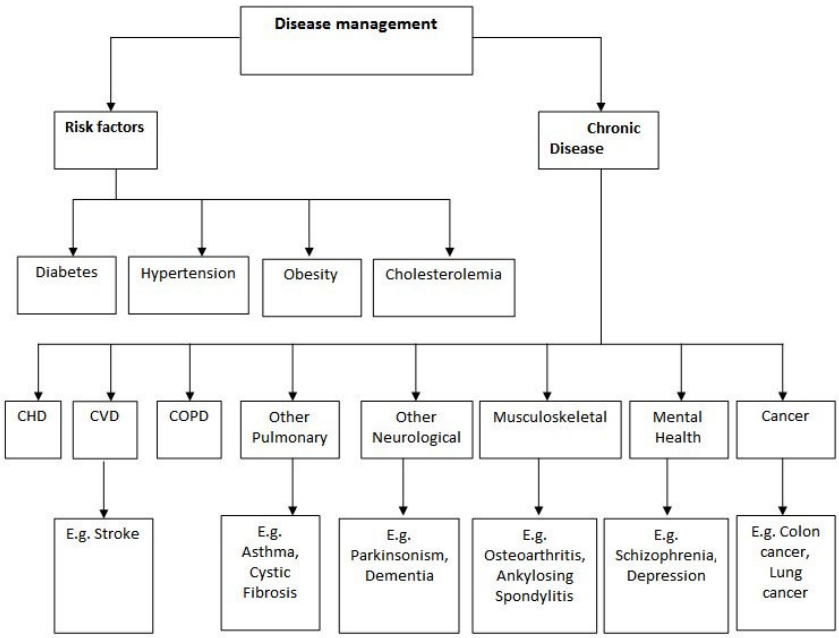
Interactive ATCS should have an automated function such as automated tailored feedback based on individual progress monitoring (e.g. comparison to norms or goals, reinforcing messages, coping messages, and automated follow-up messages). 'ATCS Plus' interventions will be included if the study explicitly reports that the effects of the intervention can be attributed to the ATCS component.

In addition, the intervention should fall within one or more types of primary preventive healthcare, or one or more types of long-term conditions management, as illustrated in Figure 1 and Figure 5, respectively.

Figure 5. Management of LTCs



CHD: Coronary Heart Disease; CVD: Cerebro Vascular Disease; COPD: Chronic Obstructive Pulmonary Disease

We will exclude studies in which interventions:

- target health professionals or teachers for educational purposes;
- are exclusively for the purpose of electronic history-taking or risk assessment with no health promotion or interactive elements;
- involve only a non-ATCS component such as face to face communication or written communication;
- are web-based interventions that are accessed via a mobile phone; or
- evaluate the groups that receive similar ATCS components but the interventions differ only by the advanced communicative functions (such as access to an advisor) or supplementary functions (such as email and short messaging service).

Control

Comparisons will be made against usual care (i.e. no ATCS intervention). We will also include comparisons of one type of ATCS

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against another, or the same type of ATCS being delivered via different delivery modes (e.g. landline telephone versus mobile phone).

Types of outcome measures

Primary outcomes

Primary outcomes consist of health behaviour, and clinical outcomes (for management of long-term conditions) (defined below). For each study we will select only one primary outcome related to health behaviour e.g. studies of ATCS for nutrition will have 'dietary intake' as the selected outcome. Multicomponent interventions, such as ATCS for nutrition and physical activity, may have multiple primary outcome measures (e.g. both dietary intake and physical activity measures). However to select only one outcome when multiple outcomes could be used, we will use the following approach (used in previous EPOC reviews (Brennan 2009; Grimshaw 2003; Hróbjartsson 2010; Jamtvedt 2006)):

- Select the primary outcome which has been identified by the publication authors (we will take into consideration the possibility of selective outcome reporting bias; we will attempt to compare the primary outcomes stated in the protocol with the ones listed in the review, to assist our judgement of this).

- When no primary outcome has been identified, select the one specified in the sample size calculation.

- If there is no sample size calculation, rank the effect estimates and select the median effect estimate.

We will report the following outcomes in the Summary of Findings table:

1. Health behaviour outcomes (category): changes in health-enhancing behaviour (e.g. physical activity), or risk-taking behaviour (e.g. tobacco consumption).

This outcome can be self-reported or collected using a validated questionnaire that can be either self-administered or interview-administered. In studies that measure the same outcome using both a self-reported measure and an objective measure, we will use the objective measure. For example, if a study on physical activity measures metabolic equivalent unit (MET) scores using a self-reported 7-day physical activity recall as well as using a pedometer, we will use the score obtained from the pedometer. Decisions on objective measures used will be documented in the Characteristics of Included Studies table.

2. Clinical outcomes (category): changes in physiological measures (e.g. blood pressure), blood biochemistry (e.g. glucose levels).

Secondary outcomes

1. Process outcomes (category): change in acceptability of service (e.g. consumer accessibility and usability of the interventions to apply information and support supplied through ATCS), satisfaction (e.g. patient and carer satisfaction with the intervention or compliance (e.g. patient compliance with the treatment or medication and factors affecting compliance).

2 Cognitive outcomes (category): changes in knowledge (i.e. knowledge of risk/accurate risk perception), attitude and intention to change, and/or self-efficacy (i.e. a person's belief in their capacity to carry out a specific action).

3. Adverse outcomes: Data on unintended adverse events attributable to the intervention.

Search methods for identification of studies

Electronic searches

We will search the following electronic databases:

- The Cochrane Consumers and Communication Review Group Specialised Register;
- The Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library*, latest issue);
- MEDLINE (OvidSP) (1980 to present);
- EMBASE (OvidSP) (1980 to present);
- PsycINFO (OvidSP) (1980 to present);
- CINAHL (EbscoHOST) (1980 to present);
- Global Health (OvidSP) (1980 to present);
- WHOLIS (1980 to present);
- LILACS (1982 to present);
- Web of Science (1980 to present); and
- ASSIS (ProQuest) (1987 to present).

The strategy for MEDLINE (OvidSP) is presented in Appendix 1.

We will search databases from 1980 onwards for the following reasons: 1) we expect that any evidence prior to 1980 will be incorporated into subsequent research; and 2) technology has advanced dramatically over the last thirty years and integration of older research should be interpreted only in light of the new findings.

Strategies will be tailored to other databases and reported in the review.

There will be no language restrictions.

Searching other resources

We will search the grey literature (e.g. Dissertation Abstracts, Index to Theses, Australasian Digital Theses).

We will contact experts in the field and authors of included studies for advice as to other relevant studies. We will also search reference lists of relevant studies, including all included studies and previously published reviews.

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We will also search online trial registers (e.g. Current Controlled Trials, www.controlled-trials.com; www.clinicaltrials.gov) for ongoing and recently completed studies.

Data collection and analysis

Selection of studies

We will merge search results across databases using the reference management software EndNote, and remove duplicate records of the same report. Two authors (LF and LCG) will then independently examine titles and abstracts of records retrieved from the search. We will retrieve the full text of the potentially-relevant studies and assess their eligibility using the inclusion criteria. Multiple reports of the same study will be linked together, in order to determine if the study is eligible for inclusion. Authors will correspond with each other to make final decisions on study inclusion and will resolve disagreement about study eligibility by discussion with a third review author (YP).

If disagreement is not resolved, then we will place the article with those 'awaiting assessment' and will contact the study author for clarification. We will also include any on-going trials if a study author(s) provides interim outcome data, or the final data, ahead of publication of their report. We will describe all the potentially-relevant excluded studies in the 'Characteristics for Excluded Studies' table along with reasons for exclusion. We will use an adapted PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow-chart to describe the study selection process (Higgins 2011).

Data extraction and management

Two authors (LF and LCG) will independently extract relevant population and intervention characteristics from all the included studies using a standard data collection form; any disagreements will be resolved by discussion. Any relevant missing information on the trial will be sought from the original author(s) of the article, if required. LF will transfer the data from the extraction form into the Review Manager software while LCG will confirm the accuracy of the transferred data.

The Cochrane Equity Methods Group checklist (Equity Checklist 2009) will be used as part of the methods to conduct the review. This will substantially enhance our reporting and analysis of population groups who may be missed.

Assessment of risk of bias in included studies

All studies meeting the inclusion criteria will be included regardless of the outcome of the assessment of risk of bias. We will assess and report on the methodological risk of bias of included studies in accordance with the Cochrane Handbook (Higgins 2011) and the guidelines of the Cochrane Consumers and Communication Review Group (Ryan 2011), which recommends the explicit reporting of the following individual elements for RCTs: random sequence generation; allocation sequence concealment; blinding (participants, personnel); blinding (outcome assessment); completeness of outcome data, selective outcome reporting; other sources of bias. If quasi-randomised controlled trials, controlled before and after studies and/or interrupted time series studies are included in the review, we will assess their risk of bias systematically utilising adaptations to the above tool.

With studies that have used CBA or ITS designs, we will use the risk of bias criteria suggested by the Cochrane Consumer and Communication Review Group (Ryan 2011).

We will refer to the guidance provided by the Cochrane Consumer and Communication Review Group (Ryan 2011) to narratively describe the results of risk of bias of each domain, for each included study. We will report our assessment of risk of bias for each domain, for each included study, with a descriptive summary of our judgment.

In all cases, two authors (LF and LCG) will independently assess the risk of bias of included studies, with any disagreements resolved by discussion and consensus. We will contact study authors for additional information about the included studies, or for clarification of the study methods as required. We will incorporate the results of the risk of bias assessment into the review through standard tables, and systematic narrative description and commentary about each of the elements, leading to an overall assessment of the risk of bias of included studies and a judgment about the internal validity of the review's results.

Measures of treatment effect

For dichotomous data, we will report risk ratios. For studies that report odds ratios, we will convert these results to risk ratios.

For continuous data from studies that assess the same outcome measure, we will estimate mean differences (for studies using the same scale) and standardized mean differences (for differences in scale) between groups For CBA studies we will report relative percentage change post intervention and standardized mean differences.

We will report all data with their 95% confidence interval (Table 1). Where follow-up data were collected at different time periods, we will report results taken from the furthest points in time relative to the intervention.

For ITS studies we will report the following estimates, and their P values, from regression analyses which adjust for autocorrelation: (i) change in level of the outcome at the first point after the introduction of the intervention (immediate effect of the intervention), (ii) the post-intervention slope minus the pre-intervention slope (long-term effect of the intervention) (Brennan 2009).

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Unit of analysis issues

Where a study has more than one active treatment arm, data from the appropriate arms for each of our main comparisons will be extracted. If more than one treatment arm is relevant for a single comparison, data from all appropriate arms will be included in that comparison, and the comparator arm will be split equally between each treatment arm, so that double counting of data does not occur. In studies where the effects of clustering have not been taken into account, we will adjust the standard deviations by the 'design effect', using intra-class coefficients if given in papers, or using external estimates obtained from similar studies (Ukoumunne 1999) as advised by Higgins 2011.

Dealing with missing data

We will conduct an intention-to-treat analysis, including all those who were randomised to either the ATCS group or control, regardless of losses to follow-up and withdrawals (Higgins 2011). Wherever possible, we will attempt to obtain missing data (e.g. number of participants in each group, outcomes and summary statistics) from the original author(s). For dichotomous outcomes, data imputed case analysis can be used to fill in missing values. This strategy imputes missing data according to reasons for 'missingness' and which essentially averages over several of the specific imputation strategies (Higgins 2008). If the standard deviations of continuous outcome data are missing, then we will try to calculate the standard deviations from other statistics, such as 95% confidence intervals, standard errors, or P values. If these are unavailable, then we will contact the author or impute the standard deviations from other similar studies (Higgins 2008).

Assessment of heterogeneity

We will assess the heterogeneity meta-analysed data by a visual inspection of the forest plot (providing a minimum of ten studies are included) and by using the Chi^2 test (with a significance level of 0.10 in consideration of the low power of such tests). We will quantify heterogeneity using the I^2 statistic; we will examine the I^2 statistic that will describe the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error, where values of 50% or more indicate a substantial level of heterogeneity (Higgins 2011). We will also take into account clinically-relevant heterogeneity issues.

Assessment of reporting biases

We will evaluate funnel plots for asymmetry (providing there are at least ten included studies in the meta-analysis). We will compute a 95% confidence interval on the expected variability of the research (to be displayed on the sides of the funnel plot).

Funnel plots will be used as a means of investigating small study effects that may have occurred due to the potential existence of reporting biases (e.g. small study bias), to examine whether the association between estimated intervention effects and a measure of study size is greater than might be expected to occur by chance, and to add further consideration to the visual inspection of the funnel plot (Higgins 2011; Sterne 2011). We will also consider other reasons for possible funnel plot asymmetry such as true heterogeneity or the risk of bias in included studies.

Data synthesis

Our decisions to meta-analyse or not will be based on an assessment of whether participants (settings), intervention, comparison and outcomes are sufficiently similar to ensure a clinically meaningful result. We expect our included studies to be clinically heterogeneous (i.e. dissimilar in terms of the above mentioned terms) giving rise to statistical heterogeneity. Therefore if a meta-analysis is appropriate, we will use a random-effects model. We will display the results of the meta-analysis in a forest plot that provides effect estimates and 95% confidence intervals for each individual study as well as a pooled effect estimate and 95% confidence interval.

If suitable numerical data are not available and/or if meta-analysis is not appropriate (as in cases where there is an unclear or high risk of bias for both allocation concealment and sequence generation, or where the included studies are simply too heterogeneous to be combined), we will then perform a narrative synthesis of the evidence and present the summarised results in a table. We will refer to the narrative synthesis framework to guide this process (Rodgers 2009). We will use the following steps to describe the studies:

- develop a preliminary synthesis by grouping the included studies by the type of primary prevention or long-term condition (in the case of management of long-term conditions) and intervention;
- describe the inclusion criteria (especially participants, interventions, comparators, and outcome elements) along with the reported findings for each of the included studies;
- include an additional table to describe the intervention components including the type of ATCS; behaviour change theories; behaviour change techniques (Michie 2011); content delivery; frequency, intensity and duration of the intervention; interaction mode; and data entry method;
- explore the relationships between characteristics of individual studies and their reported findings as well as those between the findings of different studies;
- describe the moderators as well as the mediators that would have an impact on the intervention effects; and
- use the summary of the risk of bias of an outcome across studies to judge the robustness of the evidence.

We will not meta-analyse the CBA and ITS study results; instead, we will use the narrative synthesis framework, described above, to report such results.

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We will perform the statistical analysis using RevMan version 5.2. We will adhere to the statistical guidelines described in Higgins 2011.

We will use the GRADE system to assess the quality of the evidence, the magnitude of effect of the interventions examined, and the sum of available data on the main outcomes, and to produce a Summary of Findings table (Higgins 2011). We will present one table for each different interventional comparison (e.g. ATCS versus no ATCS), and present broad outcome results by outcome categories (e.g. for the health behavior outcome category, we will present the results under the two broad subheadings: health-enhancing behaviour and risk-taking behaviour).

Subgroup analysis and investigation of heterogeneity

We will conduct subgroup analyses depending on the types of long-term condition being managed (Figure 5) and primary preventive healthcare (Figure 1). If there is substantial heterogeneity in the pooled effect between the intervention and the control group, we will assess the causes of heterogeneity and explore subgroup effects using a random effects meta-analysis. These include:

- type of ATCS (Unidirectional, Interactive or ATCS Plus);
- type of primary preventive health care (Figure 1);
- type of long-term conditions (Figure 5);
- language (for studies in languages other than English);
- country's income level (for studies undertaken in 'high income countries', 'middle income countries', or 'low income countries' as defined by the World Bank's Income Level data (World Bank 2012));
- source of funding (Industry versus other); and
- theoretical models (where applicable, included studies will be separated depending on the type of theoretical model that has been used to inform the design of the intervention).

If at least 10 studies are available for each outcome, we will perform meta-regression. This will be implemented in Stata using the 'metareg' command and including trial characteristics as covariates.

As we intend to include many variables, to reduce misleading conclusions resulting from multiple statistical analyses we will interpret statistically significant findings in the context of how many analyses were undertaken and adjust the level of significance to account for making multiple comparisons, with the assistance of a statistician (LG).

Sensitivity analysis

We will consider performing sensitivity analyses (using the criteria discussed in the 'Assessment of risk of bias in included studies' section, and as recommended by Higgins 2011) including:

- studies with low risk of bias in the selection bias domain, i.e. sequence generation and allocation concealment
- studies with low risk of bias in the attrition bias domain, i.e. incomplete outcome data
- fixed-effect model for all the studies
- fixed-effect model for studies with low risk of bias in the selection bias domain
- fixed-effect model for studies with low risk of bias in the attrition bias domain

Consumer participation

Involvement of non-governmental organisations that represent a range of potential user groups will be an important part of the project development. We will contact non-governmental organisations such as the Diabetes Research Network and request one of their members to represent in our steering committee meetings to guide us in the review process, particularly in considering outcomes of interest to users, and methods of disseminating results to user communities. This protocol has been peer reviewed by at least one consumer, as part of the Cochrane Consumers and Communication Review Group's standard editorial process; the review will likewise be peer reviewed by at least one consumer. We will also seek additional feedback from members of the Cochrane Consumer Network at draft review stage.

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